

Notice of Allowability

Application No.

09/882,509

Examiner

Maryam Monshipouri

Applicant(s)

KUPPUSAMY ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1,3-5 and 8-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>filed 12/29/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____ |

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Joseph Leone, on 12/29/2005.

Examiner's Amendment to the Claims

Cancel claims 2, 6-7, 12-21.

In claim 1, line 2, after "to 3' order a", insert --- $\lambda pR-\lambda pL$ ---.

In claim 1, line 4, after "as encoded", delete "in" and substitute therefor --- by ---.

In claim 4, line 3, after "to 3' order a", insert --- $\lambda pR-\lambda pL$ ---.

In claim 4, line 5, after "as encoded", delete "in" and substitute therefor --- by ---.

In claim 11, line 4, at the beginning after "a", insert --- $\lambda pR-\lambda pL$ ---.

The following is an **Examiner's Statement of Reasons for Allowance**:

Claims 1, 3-5, 8-11 are directed to a high level expression construct comprising a specifically Lamnda promoter and a *S. equisimillis* H46A streptokinase encoding sequence (skc gene) wherein the expression construct drives formation of inclusion bodies comprising streptokinase (SK) in a host cell comprising said construct wherein said streptokinase is enzymatically active upon solubilization of the inclusion bodies as well as host cells comprising said construct and methods of expressing streptokinase utilizing said construct.

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Claimed construct is free of prior art. Further, even though the closest prior art (Pupo et al., Biotechnology Letters, 21, 1119-1123, 1999) teaches methods of expressing said skc gene in solubilized form, it fails to teach a high expression level DNA construct for recombinantly expressing skc gene in inclusion bodies. In fact, Pupo et al. teaches away from recombinantly expressing streptokinase gene in inclusion bodies because it teaches that streptokinase expressed in inclusion bodies is highly aggregated and needs very harsh conditions for solubilization.

Hence, said high expression construct for preparation of streptokinase in inclusion bodies is novel and non-obvious over the prior art. Since said construct is novel and non-obvious, claimed host cells comprising said product and claimed method of use of said construct are also novel and non-obvious.

Claims 1, 3-5, 8-11 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maryam Monshipouri Ph.D.

Primary Examiner
